

DOCKET NO.: 261088US0/kmm

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

GROUP: 1616

Navroz BOGHANI, et al.

SERIAL NO: 10/719,298

EXAMINER: KONATA, M.

FILED: November 21, 2003

FOR: DELIVERY SYSTEM FOR ACTIVE COMPONENTS AS PART OF AN
EDIBLE COMPOSITION HAVING PRESELECTED TENSILE STRENGTH

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

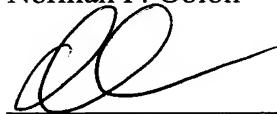
This request is being filed with a Notice of Appeal.

The review is requested for the reason(s) stated on the attached sheet(s). No more than five (5) pages are provided.

I am the attorney or agent of record.

Respectfully Submitted,

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IN RE APPLICATION OF :
NAVROZ BOGHANI, ET AL. EXAMINER: GEORGE, KONATA M.
SERIAL NO: 10/719,298 :
FILED: NOVEMBER 21, 2003 GROUP ART UNIT: 1616
FOR: A DELIVERY SYSTEM FOR :
ACTIVE COMPONENTS AS PART OF AN
EDIBLE COMPOSITION HAVING
PRESELECTED TENSILE STRENGTH

PRE-APPEAL CONFERENCE BRIEF

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Please reconsider the above-identified application based on the following:

Remarks begin on page 2 of this paper.

REMARKS

Claims 1-37, 47, 64-70 and 88-92 are active in this application.

The question presented here is simple: What is the legal requirement for inherency and does the cited art of Kitajima and Schobel inherently meet the claims? For the reasons explained below, Kitajima and Schobel do not inherently describe what is claimed.

As noted by the court in *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323 (CCPA 1981), the mere fact that a certain thing may result from a given set of circumstances is not sufficient to prove inherency. Inherency may not be established by probabilities or possibilities. Something that is inherent must inevitably be the result each and every time.

The delivery systems of the cited Kitajima and Schobel patents would not inherently achieve a tensile strength of at least 10,000 psi as set forth in Claim 1 of the present application. In particular, the methodologies employed by Kitajima and Schobel utilize solvents that become part of the composition and as a result would generally result in tensile strengths much lower than that which is claimed due to the inevitable remaining solvent or solvent residue and the morphology of the encapsulated materials that would result from Kitajima and Schobel's processes. Thus, the process used by Kitajima and Schobel changes the composition of the delivery system and eliminates the claimed tensile strength element from each and every delivery system in Kitajima and Schobel.

In the Advisory Action maintaining the rejections of record, the Examiner stated that “[s]ince the prior art references of Kitajima and Schobel teach the claimed encapsulating material, the tensile strength would also be the same. Applicant is reminded that the claim is directed to a composition and not a method of making.”

Applicants respectfully submit that the point was missed.

First an analogy simply for illustration. Oil and water. Put those into a tube with an emulsifier without mixing. What do you have? Two separate phases, e.g., water sitting on top of the oil.

Now, mix the water, oil and emulsifier to make an emulsion. While the step of mixing is an active step attributed to methods, it causes the emulsion to be a fundamentally different composition from the first composition composed of two separated phases, even though the two compositions have the same ingredients. That is, the emulsion is NOT inherently the same as the two-phase composition.

Turning now to the facts of the present case and the cited art. It is again noted that even though Kitajima and Schobel may describe the same starting materials to prepare the “capsules” and this is relevant, it is not determinative. Indeed, how the active is encapsulated and the properties of the end product (defined by tensile strength) are the relevant issues to assess and because the rejections do not discuss why it is believed that the cited end products (the “capsules”) would necessarily have the tensile strength defined in the claims, the Office has not met its burden showing that the cited materials necessarily, each and every time meet what is claimed in the present application. So here that Kitajima and Schobel describe an encapsulating material and active (analogous to water and oil), the end product or capsules that are described by Kitajima and Schobel do not inherently have the tensile strength that is claimed.

As explained previously, the tensile strength of a composition will depend on the composition itself, the morphology of the solid material distributed in the composition and solvent residue. Indeed, even minor amounts of solvent, e.g., about 0.5%, have a dramatic lowering effect on the tensile strength of the encapsulation.

Kitajima describes a process for the preparation of capsules containing a core material, where the core material is dispersed in a solution of an organic solvent and an encapsulating material. (see col. 1, lines 40-45). The suspension (core material and encapsulating material/solvent) is then dispersed in an aqueous salt solution and then the organic solvent is removed (*Id.*). Kitajima emphasizes the necessity of the solvent in the process because it is the selection of solvent that is asserted as the invention (col. 1, line 63 to col. 2, line 7; col. 3, lines 44-47; lines 49-52; and col. 4-8 in Example 1). This Kitajima process results in capsules with core shell type morphology, see e.g., col. 3, lines 59-65 (See also FIG. 1 and FIG. 2 of Kitajima).

Such a thin layer of encapsulating material surrounding the active core would not necessarily have a tensile strength anywhere close to 10,000 psi (as in the claims). Further, under the conditions Kitajima describes for removing the solvent after dispersion (see above), no matter how hard one tries there will be a remaining solvent residue in the end product capsules. Because of the core shell morphology and solvent residue, the end product capsules will not, each and every time, have the minimum tensile strength as claimed.

Like Kitajima, Schobel does describe an encapsulated sweetener where the coating material comprises a hydrophobic polymer and a hydrophobic plasticizer and the polymer can be polyvinyl acetate phthalate (see col. 3, lines 37-42 and col. 7, lines 14-26). Schobel describes in the paragraph bridging col. 8-9 that the encapsulation is prepared by spray drying, coacervation, or a fluidized bed coating process. Each of these procedures utilizes a solvent to prepare an encapsulation. In the instance of spray drying, the polymeric material is dissolved in a solvent and sprayed onto the sweetener. The coacervation technique involves mixing solvents containing the sweetener and the polymer and in the fluidized bed, much like

the spray drying technique, the solvent dissolved polymer is passed through a specialized apparatus to effect coating (see also col. 9, lines 1-16 of Schobel). See also col. 10-12.

The morphohology and residual solvent in the spray encapsulated material, the coacervation process, and the fluidized bed coating process described by Schobel will not, each and every time, have the minimum tensile strength as claimed. That is, as explained in the context of the Kitajima rejection, (1) the coating of polymer that surrounds the sweetener would not have sufficient thickness to impart any appreciable amount of tensile strength to the level that is claimed; and (2) the residual solvent that would remain would preclude those compositions from inherently achieving a 10,000 psi tensile strength.

Favorable reconsideration and allowance of all pending claims is requested.

Respectfully submitted,

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